Food and Drug Administration
Center for Drug Evaluation and Research

Pediatric Subcommittee
of the Oncologic Drugs Advisory Committee

Advisors and Consultants Conference Room
5630 Fishers Lane
Rockville, Maryland

Tentative Agenda — June 28, 2001

The purpose of this meeting is to provide advice to the FDA on when pediatric solid tumors and CNS malignancies may be considered to be the same indication as adult malignancies.

The Pediatric Rule of 1998 states that there is a Federal mandate to perform pediatric studies if the indication under review for a marketing license exists in children.

Based on conventional criteria, the different tumor types seen in adults and children may appear to limit the application of the 1998 Pediatric Rule to pediatric oncology. Data other than conventional histology may extend the consideration of what is a pediatric disease and what is an adult disease.

8:00	Call to Order and Opening Remarks	Victor Santana, M.D. Chair, Pediatric Subcommittee of ODAC
	Welcome	Richard Pazdur, M.D. Director, Division of Oncology Drug Products
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
8:15	Open Public Hearing (*30 minutes allocated unless public participation does not last that long*)	
8:45	Charge to the Committee	Steven Hirschfeld, M.D., Ph.D. Medical Officer, DODP
8:50	Challenges and Considerations in Linking Adult and Pediatric Solid Tumors	Victor Santana, M.D. St. Jude Children's Research Hospital
9:15	Challenges and Considerations in Linking Adult and Pediatric CNS Malignancies	Henry S. Friedman, M.D. Duke University Medical Center
9:40	Discussion	
10:00	Break	

10:15	Perspectives on Sarcomas	Michael P. Link, M.D. Stanford University School of Medicine Robert S. Benjamin, M.D. University of Texas M.D. Anderson Cancer Center
10:45	Discussion	

Questions to the Committee

I. For sarcomas

A. What general principles could be used to relate sarcomas in adults to sarcomas in children?

B. Which of the following adult diseases has a pediatric counterpart and what is the basis?

1. *Soft tissue sarcomas*
2. *Tumors of bone*
3. *Tumors of the vasculature*
4. *Gastrointestinal carcinomas*

C. Are there pediatric sarcomas that have an adult counterpart that is not commonly classified as an adult sarcoma, but as some other type of adult malignancy such as a carcinoma?

11:45	Lunch	
12:30	Open Public Hearing (*30 minutes allocated unless public participation does not last that long*)	
1:00	Perspectives on Lung Tumors and Neuroblastoma	Frederic Kaye, M.D. National Cancer Institute C. Patrick Reynolds, M.D., Ph.D. Children's Hospital of Los Angeles
1:30	Discussion	

Questions to the Committee

II. For lung tumors and neuroendocrine tumors:

A. What general principles could be used to relate malignancies in adults to neuroendcrine malignancies in children?

B. Which of the following adult diseases has a pediatric counterpart and what is the basis?

1. *Small cell lung cancer*
2. *Non-small cell lung cancer*
3. *Mesothelioma*
4. *Bronchiogenic tumors*
5. *Endocrine tumors*
   - *(i) Thyroid carcinoma*
   - *(ii) Multiple endocrine neoplasias*
6. *Adrenal tumors other than neuroblastoma*

B. Are there pediatric neuroendocrine tumors that have an adult counterpart that is not commonly classified as an adult neuroendocrine tumor, but as some other type of adult malignancy such as a carcinoma?

2:00	Perspectives on CNS Malignancies	Susan Staugaitis, M.D., Ph.D. The Cleveland Clinic Foundation Howard A. Fine, M.D. National Institutes of Health
2:30	Break	
2:45	Discussion	

Questions to the Committee

III. For CNS malignancies

A. What general principles could be used to relate CNS malignancies in adults to CNS malignancies in children?

B. Which of the following adult diseases has a pediatric counterpart and what is the basis?

- *(1) Central nervous system tumors*
  - *(a) Neuroectodermal tumors*
  - *(b) Nerve sheath tumors*
  - *(c) Meningeal tumors*
  - *(d) Germ cell tumors*
  - *(e) Germinomas*
  - *(f) Cyst like lesions*
  - *(g) Sellar tumors*
    - *(i) Pituitary adenoma*
    - *(ii) Craniopharyngioma*

C. Are there pediatric CNS malignancies that have an adult counterpart that is not commonly classified as an adult CNS malignancy, but as some other adult malignancy such as a germ cell tumor or other type of tumor?

3:40	Summary Comments	Paul A. Meyers, M.D. Memorial Sloan-Kettering Cancer Center Victor A. Levin, M.D. University of Texas MD Anderson Cancer Center
4:00	Adjourn	